

NEBRASKA BOARD OF PHARMACY
MEETING MINUTES
March 9, 2015

ROLL CALL

Jennifer King, R.P., Chair, called the meeting of the Board of Pharmacy to order at 8:30 a.m. in the Lighthouse Room of the Country Inn & Suites, located at 5353 North 27th Street, Lincoln, Nebraska. The agenda was provided to Board members, posted on a public bulletin board in the Nebraska State Office Building, posted on the Department's website, and e-mailed to the "interested parties" list prior to the meeting. The following Board members answered roll call:

Jennifer King, R.P., Chair
Patricia Gollner, R.P., Vice-Chair
Michael Losee, Secretary
Kenneth Saunders, R.P.
Robert Marshall, R.P.

A quorum was present and the meeting convened.

Also present were: Lisa Anderson, Assistant Attorney General; Mike Rueb, R.P., Pharmacy Inspector; Gary Cheloha, R.P., Pharmacy Inspector; Dean Willson, Jr., R.P., Pharmacy Inspector; Becky Wisell, Unit Administrator; Kathie Lueke, Program Manager; Vonda Apking, Health Licensing Coordinator; Kevin Griess, Department Legal; Jeff Newman, Investigator; Russ Fosler, Investigator; and Larry Wiehn, Investigator; Peggy Persell, Program Manager, Investigations Unit.

King announced that there is a copy of all the public documents being reviewed at this meeting available in the meeting room pursuant to the Open Meetings Act.

Wisell introduced Kathie Lueke as the new Program Manager for the Office of Medical and Specialized Health. Lueke provided some employment background to the Board members.

REVIEW OF AGENDA

Adoption of Agenda

Marshall moved, seconded by Saunders, to approve the agenda as presented with the Chair having the authority to rearrange as needed. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: none. Motion carried.

Additions, Modification, Reordering

The Board requested that the following applications be removed from the consent agenda:

Alexe Anderson – Pharmacy Technician application
Annette Nichols – Pharmacy Technician application
Delena Dominguez – Pharmacy Technician application
Katherine McCurdy – Pharmacy Technician application
Misty Orteiz – Pharmacy Technician application
Miya Hicks – Pharmacy Technician application
Stewart Solsky – Pharmacy Technician application
Tarah Otterstad – Pharmacy Technician application
Tonya Whitebull – Pharmacy Technician application
Kristi Meinke – Pharmacy Technician Reinstatement application
Jessica DiLeo – Pharmacist application
Richard Chang – Pharmacist application
Goot Nursing Home dba PharMerica – Mail Service Pharmacy application

Adoption of Consent Agenda

Marshall moved, seconded by Losee, to approve the consent agenda as amended. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: none. Motion carried.

INVESTIGATIONAL REPORTS, DISCIPLINARY REPORTS, CONTROLLED SUBSTANCES AUDIT REPORTS & APPLICATION REVIEW – CLOSED SESSION

Gollner moved, seconded by Losee, to close the session at 8:37 a.m. to review investigational reports, disciplinary reports, controlled substances audit reports and applications. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: none. Motion carried.

Griess left the meeting at 8:54 a.m.
Griess rejoined the meeting at 9:05 a.m.

Marshall recused himself from the meeting at 9:05 a.m.
Marshall returned to the meeting at 9:29 a.m.

Griess left to meeting at 10:56 a.m.
Griess rejoined the meeting at 11:08 a.m.

Marshall moved, seconded by Gollner, to open the session at 11:09 a.m. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: none. Motion carried.

APPROVAL OF MINUTES

January 16, 2015

Page 1: Add that Gollner was absent.

Page 2: No changes.

Page 3: Under Opinion of the Board Regarding Pharmaceutical care Agreements and Adjusting Medications versus Prescribing New Medication, line 2, change the word "does" to "do"; line 3, delete the word "traditionally"; under Hospice Prescriptions, line 1, change to word "does" to "do"; under Office Use Compounding for Veterinary Drugs, line 3, change the last "is" to "has been"; line 4, change the word "is" to "has been", use the correct name of the federal act; and after the name of the federal act add "does prohibit office use compounding but"; under PRESCRIBERS AND PRESCRIBING AUTHORITY CHART, line 2, add an "s" to the word "podiatrist" and line 5, use the correct spelling for "aliments"; under NATIONAL ASSOCIATION OF BOARDS OF PHARMACY (NABP) ISSUES, correct the spelling of "NATIONAL".

Page 4: Add a space between the paragraph under Communication with Board Members and the next title; under LB50 – Change provisions relating to medicaid covered services, capitalize the word "Medicaid"; under LB 115 – Prohibit certain actions related to social security numbers, after the word "not" add "impact the Board because the Uniform Credentialing Act (UCA) requires" and add "a" after the word "already"; under LB369 – Change provisions to impaired credential holders under the Uniform Credentialing Act, line 1 change the word "American's" to "Americans".

Page 5: Fix the spacing; under LB567 – Permit transfer of prescription information between pharmacies as prescribed, line 2, change the word "support" to "oppose" and add "because it proposes a change that will conflict with current requirements of the U.S. Drug Enforcement Administration (DEA) that are found in the Code of Federal Regulations (CFR)." after LB567.

Marshall moved, seconded by Saunders, to approve the January 16, 2015 minutes as corrected. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

March 4, 2015 – Conference Call

Under Adoption of Agenda, line 1, change the motion to be "to approve the agenda as presented"; under LB 471, line 2, change the word "giving" to "give". Marshall moved, seconded by Gollner, to approve the March 4, 2015 minutes as corrected. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

BOARD RECOMMENDATIONS ON APPLICATIONS FOR LICENSURE AND REGISTRATION

Pharmacy Technician Application(s)

Marshall moved, seconded by Gollner, to postpone action on the pharmacy technician registration application of Alexe Anderson for additional information. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Gollner moved, seconded by Saunders, to postpone action on the pharmacy technician registration application of Annette Nichols for additional information. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Losee moved, seconded by Saunders, to deny the pharmacy technician registration application of Delena Dominguez. The basis for this denial is misrepresentation of material facts in procuring a credential. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Marshall moved, seconded by Saunders, to postpone action on the pharmacy technician registration application of Katherine McCurdy for additional information. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Gollner moved, seconded by Marshall, to recommend issuing a pharmacy technician registration to Misty Orteiz. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Marshall moved, seconded by Gollner, to postpone action on the pharmacy technician registration application of Miya Hicks for additional information. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Saunders moved, seconded by Gollner, to recommend issuing a pharmacy technician registration to Stewart Solsky. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Saunders moved, seconded by Losee, to postpone action on the pharmacy technician registration application of Tarah Otterstad for additional information. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Gollner moved, seconded by Marshall, to deny the pharmacy technician registration application of Tonya White Bull. The basis was because of her conviction history and lack of good character. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Marshall moved, seconded by Saunders, to issuing a pharmacy technician registration of Franklin Ansu. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Pharmacy Technician Reinstatement Application(s)

No additional action needed on the reinstatement application of Kristi Meinke.

Pharmacist Application(s) - CONSENT

Gollner moved, seconded by Marshall, to recommend issuing a pharmacist license to Jessica DiLeo. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Marshall moved, seconded by Losee, to postpone action on the pharmacist licensure application of Richard Chang for additional information. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Mail Service Pharmacy Application(s) - CONSENT

Gollner moved, seconded by Saunders, to postpone action on the mail service pharmacy application of Goot Nursing Home dba PharMerica for additional information. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Mail Service Pharmacy Renewal Application(s) - CONSENT

REVIEW OF PHARMACEUTICAL CARE AGREEMENTS – CONSENT

PHARMACY TECHNICIAN MANUAL(S) – CONSENT

UPDATE ON 2015 LEGISLATION

LB37 - Adopt the Prescription Drug Safety Act and change and transfer pharmacy, prescription, and drug provisions

This bill is on final reading.

LB115 - Prohibit certain actions related to social security numbers

No discussion on this bill.

LB189 - Change provisions and penalties relating to marijuana and alphabetize definitions

No discussion on this bill.

LB264 - Provide for issuance of credentials under the Uniform Credentialing Act based on military education, training, or experience

No discussion on this bill.

LB369 - Change provisions relating to impaired credential holders under the Uniform Credentialing Act

No discussion on this bill.

LB332 - Appropriate funds for the statewide prescription drug disposal project

No discussion on this bill.

LB342 - Permit insurers to contract for pharmacist professional services

No discussion on this bill.

LB390 - Provide for the medical use of cannabidiol as prescribed and create the Medical Cannabidiol Pilot Study

No discussion on this bill.

LB452 - Change provisions relating to advertisement by credential holders

This bill is on general file. No other discussion on this bill.

LB471 - Change provisions relating to prescription drug monitoring

Marshall commented that he provided testimony as an individual pharmacist for a prescription drug monitoring program that is comparable to other states. Marshall also explained that Danna Droz, Prescription Monitoring Program Liaison, NABP will be her later to answering any question the Board may have about how to implement a Prescription Drug Monitoring Program (PDMP).

LB546 - Authorize administration of naloxone as prescribed

No discussion on this bill.

LB567 - Permit transfer of prescription information between pharmacies as prescribed

No discussion on this bill.

Joni Cover, Nebraska Pharmacists Association (NPA), mentioned that LB107 a bill that eliminates the integrated practice agreements and provides for transition-to-practice agreements for nurse practitioners was approved by the Governor on March 5, 2015.

There are several marijuana bills. The NPA is looking at all bills and is recommending that the legislature treat marijuana like all other drugs.

LB643 - Adopt the Cannabis Compassion and Care Act

Marshall moved, seconded by Losee, to not take a position on this bill and send a letter to Senator Garrett recommending that marijuana be treated like other drugs.

LB90 - Change provisions for directed review under the Nebraska Regulation of Health Professions Act

This bill was signed by the Governor on March 6, 2015.

LB129 - Require criminal background checks for applicants for an initial nursing license

This bill is in the final stages of approval.

LB369 - Change provisions relating to impaired credential holders under the Uniform Credentialing Act

This bill has not made it out of Committee. Gollner moved, seconded by Saunders, to send a letter of support. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

REQUEST FOR CLARIFICATION REGARDING THE BOARD'S POSITION ON LB567

Carey Potter, Registered Lobbyist, requested clarification on the Board's position on LB567. The Board clarified that federal law does not allow a controlled substances prescription to be transferred. Ms. Potter agreed and it was not the intent of the bill to allow transfers of controlled substances prescriptions. The bill was there to allow a transfer of an original prescription that was received by the wrong pharmacy to get it to the right pharmacy without the patient having to go back to their physician for a new prescription. The Board commented that existing statutes do not prohibit and it is the standard of practice to get the non-controlled prescription to the correct pharmacy for the patient.

FEDERAL TRADE COMMISSION VS. NORTH CAROLINA DENTAL BOARD SUPREME COURT OPINION – HOW DOES THIS OPINION AFFECT NEBRASKA BOARDS

Griess informed the Board that Department Legal and the Attorney General's office will be meeting to develop a response. Once that response is finalized then it will be brought back to the Board.

PRACTICE QUESTION(S)

Opinion of the Board Regarding Pharmaceutical Care Agreements and Adjusting Medication versus Prescribing New Medication – Board Response

The Board reviewed their response and suggested some changes to include initiating therapy based on protocols. Marshall moved, seconded by Saunders, to approve the Board's response as amended. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Full Board Response as modified:

The following regulatory language is taken from 172 NAC 128 Section 13:

128-013 PHARMACEUTICAL CARE REQUIREMENTS

128-013.01 A pharmacist may enter into a practice agreement with a licensed medical practitioner to provide pharmaceutical care according to written protocols.

128-013.02 The pharmacist must assure that the Board is notified of any practice agreement. Such notice must be given to both the Board of Pharmacy and the medical practitioner's professional Board. Such notice must contain the names of the

pharmacist(s) and the licensed medical practitioner(s) and a description of the therapy being monitored or initiated.

1. A copy of the practice agreement and written protocols must be available for review by any representative of the Department, and
2. A copy of the practice agreement or written protocols must be sent to the Board upon request from the Board.
3. Written notice must be given to the Board at initiation and at any time there is a change in parties or protocols.

128-013.03 Practice agreements and written protocols must be signed by the pharmacist and the medical practitioner and must be reviewed, signed, and dated every 12 months.

128-013.04 Practice agreements and written protocols will cease immediately upon:

1. The death of either the pharmacist or the licensed medical practitioner, or
2. Loss of license of either the pharmacist or the medical practitioner, or
3. Disciplinary action limiting the ability of either the pharmacist or the medical practitioner to enter into practice agreements, or
4. Individual decision or mutual agreement of the pharmacist(s) or medical practitioner(s) to end the agreement.

128-013.05 Nothing in these agreements will allow a pharmacist to practice beyond his/her scope of practice.

The scope of practice of a pharmacist is defined in Neb. Rev Stat. **§38-2837 as the following:** (1) Practice of pharmacy means (a) the interpretation, evaluation, and implementation of a medical order, (b) the dispensing of drugs and devices, (c) drug product selection, (d) the administration of drugs or devices, (e) drug utilization review, (f) patient counseling, (g) the provision of pharmaceutical care, and (h) the responsibility for compounding and labeling of dispensed or repackaged drugs and devices, proper and safe storage of drugs and devices, and maintenance of proper records. (2) The active practice of pharmacy means the performance of the functions set out in this section by a pharmacist as his or her principal or ordinary occupation.

Since a pharmacist is not authorized to prescribe, prescribing has not been allowed in a pharmaceutical care agreements.

Pharmaceutical care is defined in Neb. Rev. Stat. §38-2831 as follows: (1) Pharmaceutical care means the provision of drug therapy for the purpose of achieving therapeutic outcomes that improve a patient's quality of life. Such outcomes include (a) the cure of disease, (b) the elimination or reduction of a patient's symptomatology, (c) the arrest or slowing of a disease process, or (d) the prevention of a disease or symptomatology. (2) Pharmaceutical care includes the process through which the pharmacist works in concert with the patient and his or her caregiver, physician, or other professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient.

Therefore, it is the Board's opinion that a pharmacist can initiate medications and adjust medications following the specific written protocols of a pharmaceutical care agreement between the pharmacist and the licensed medical practitioner.

Also, the following opinion was issued at the Board of Pharmacy meeting on 11/18/2013: It is the opinion of the Board of Pharmacy that Rapid Diagnostic Testing and Medication Therapy Management are allowable in Nebraska based on Neb. Rev. Stat. §38-2828, §38-2831, and §38-2837 which are the definitions of medical orders, pharmaceutical care and the practice of pharmacy.

Hospice Prescriptions – Board Response

Gollner moved, seconded by Marshall, to approve the Board's response as presented. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Full Board Response:

The Board of Pharmacy has reviewed your letter dated August 14, 2014, and has discussed your questions regarding prescriptions for hospice patients at Board of Pharmacy meetings on January 26, 2015, and on March 9, 2015. Following are the Board's responses to your questions:

1. Would you please verify that pain is an emergency?

The Board of Pharmacy believes that pain can, and should be, considered as an emergency, especially for a hospice patient. The regulations for pharmacies (175 NAC 8) include section 8-006.05D which provides clarification to the meaning of an emergency situation, including when the prescriber determines that immediate administration of the controlled substance is necessary for proper treatment of the patient, no appropriate alternative treatment is available, and it is not reasonably possible for the prescriber to provide a signed, written prescription to the pharmacy.

2. Can a nurse call in a hospice prescription as an agent of the prescriber?

An agent of a prescriber cannot call in a prescription for an emergency Schedule II controlled substance prescription. A prescription for an emergency Schedule II controlled substance prescription must be communicated to the pharmacy by the prescriber. However, an "authorized agent" of the prescriber can call in prescriptions for Schedule III, IV, or V controlled substances. Nebraska does not require an agent to be "authorized" per the DEA statement of policy to call in non-controlled prescriptions.

See DEA's statement of policy in the "Federal Register/Vol. 75, No. 193/ Wednesday, October 6, 2010/Rules and Regulations" pages 61613 thru 61617.

3. Can a pharmacist dispense a hospice prescription pursuant to the phone call of an agent, regardless of where the patient lives?

Yes, providing that the prescription is not a Schedule II controlled substance. The patient is not required to be living in a hospice or other health care facility to qualify for this provision. A patient can be living in his/her own residence and would still meet the requirements of the law. The DEA does have hospice requirements for faxing a Schedule II controlled substance prescription. The hospice patient must be enrolled in a hospice care program certified and/or paid for by Medicare or hospice programs which are licensed by the State.

See DEA's statement of policy in the "Federal Register/Vol. 75, No. 193/ Wednesday, October 6, 2010/Rules and Regulations" pages 61613 thru 61617.
(See page 61614.)

4. Please verify that the signed prescription required to be on-site in the pharmacy within seven days may be written and delivered to the pharmacy or written and faxed to the pharmacy as long as the prescriber signs the prescription?

The law requires the signed emergency prescription that was communicated orally to the pharmacy for a hospice patient to be delivered in person or by mail (postmarked) to the pharmacy within seven days. Although not required to do so, many pharmacists will contact the prescriber on the sixth day to remind them to send the signed prescription. If the pharmacy has not received the signed prescription within seven days, the matter must be reported to the Drug Enforcement Administration (DEA).

See CFR 1306.11(d)(4).

The Board of Pharmacy requests that you consider writing an article on the issue of prescriptions for hospice patients that could be published in the Nebraska Pharmacists Association newsletter and shared with pharmacists across the state.

Thank you for your efforts to help clarify these statutes for pharmacists in Nebraska.

Office Use Compounding for Veterinary Drugs – Board Response

Marshall moved, seconded by Gollner, to approve the Board's response as presented. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Full Board Response:

The Board of Pharmacy was asked to clarify the requirements of a veterinarian and their compounding pharmacy to use a compounded medication for veterinary office use only for companion animals. One example provided is whether a compounded drug may be dispensed to multiple different patients or whether it must be prescribed and used by just one patient.

Neb. Rev. Stat. § 38-2840 defines prescription as “an order for a drug or device issued by a practitioner for a specific patient, for emergency use, or for use in immunizations. Prescription does not include a chart order.”

Thus, unless a prescribed compounded drug is used for an emergency or immunization, Nebraska law requires that it be used for one patient.

The Pharmacy Practice Act does not define “emergency.” Deciding what constitutes an “emergency” is left to each practitioner to decide on a case by case basis, recognizing that qualified professionals have considerable discretion in making that judgment. The United States Supreme Court has said that qualified professionals will be given deference in exercising their judgment and will not be second-guessed unless “the decision by the professional is such a substantial departure from accepted professional judgment, practice, or standards as to demonstrate that the person responsible actually did not base the decision on such a judgment.” *Youngberg v. Romeo*, 457 U.S. 307, 323 (1982).

FDA RELEASES FIVE DRAFT DOCUMENTS RELATED TO COMPOUNDING AND REPACKAGING REQUIREMENTS

Wisell explained that Lueke and Willson will be attending a Food and Drug Administration (FDA) meeting. Past opinion of the Department was not to enter into a Memorandum of Understanding (MOUs) with the FDA. Lueke and Willson will get more information whether it is important enough for the State of Nebraska to enter into a MOU with the FDA.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY (NABP) ISSUES

Danna Droz, Prescription Monitoring Program (PMP) Liaison, NABP, presented information to the Board regarding other states PMPs, pros and cons of different types of PMPs, and a brief timeline for implementing a new PMP. The Board thanked Ms. Droz.

Annual Meeting – May 16-19, 2015 – New Orleans, LA – Voting Delegate and Travel Grant Information

Staff will request travel approval for all five Board members, one inspector, and one staff. Once approval is received, staff will notify everyone that travel has been approved.

2016 District V Meeting Planning

Marshall explained the two meeting proposals provided by the Hyatt Place and Courtyard Marriott. The Board agreed to accept the proposal provided by the Courtyard Marriott. Marshall will find out the next step and reserving the meeting space and provide NABP with this information.

The Department will try to have a draft of both chapters (172 NAC 128 and 175 NAC 8) of regulations to review at the May meeting.

ADJOURNMENT

Marshall moved, seconded by Saunders, to adjourn the meeting at 1:50 pm. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Respectfully submitted,

(signature on file with the Department)

Michael Losee, Secretary
Board of Pharmacy